

## REMARKS

### **I. Status of the Claims**

Claims 14, 17, 20, and 23-25 were pending at the time of the Action. Claims 14 and 23-25 have been amended. Claims 30-38 have been added. Support for the amended claims can be found throughout the disclosure as originally filed and more particularly at least on page 4, line 26 to page 5, line 7; and from page 5, line 26 to page 6, line 3; page 6, lines 12 – 22; FIG. 2, and the claims as originally filed. Applicants note that FIG. 2 describes various amplification primers that span exons of the SCN1A gene. The specification on page 6 describes primer specific amplification of the SCN1A nucleic acid stating “. . . a pair of primers is designed to specifically amplify a segment of one of the markers [e.g., SCN1A gene]. . . .” SEQ ID NO:1 defines an mRNA or cDNA of the SCN1A that contains the sequence of the processed transcript of the SCN1A gene, *i.e.*, exons with intervening introns removed. The fragments designated by nucleotides 739-867, 3970-4143, and 5521-5747 of SEQ ID NO:1 represent those exon regions amplified by primer pairs defined in FIG. 2, *i.e.*, NaC-63/NaC-64, NaC-143/NaC-144, and NaC-262/NaC-263, respectively. Priming sites for the primers can be found in either exonic or intronic region in the following related SEQ IDs: primers NaC-63 and NaC-64 can be found in SEQ ID NO:9, primers NaC-143 and NaC-144 can be found in SEQ ID NO:25, and primers NaC-262 and NaC-263 sites can be found in SEQ ID NO:32. Therefore, written description for the nucleic acid fragments of claim 14 is present in the application as filed. No new subject matter has been added by the afore mentioned amendments.

Claims 30-38 have been added. Support for new claim 30 is found at least on page 52. Support for new claim 31 is found at least on page 27, line 16. Support for new claims 32 and 36 is found at least in Example 6 and in particular at page 55, lines 14 and 15. Support for new

claims 33 and 37 is found at least in Example 3 and in particular at page 52, lines 7 to 9; and in Figure 3. Support for new claims 34 and 38 is found at least in Example 3 and in particular at page 52, lines 15 to 18; and in Figure 3. Finally, support for claim 35 is found at least at page 4, lines 2-3; lines 19-22; and lines 26-29; at page 27, lines 3-4 and in the corresponding Figure 3; at page 27, line 16, and at page 36 from lines 27-29. No new subject matter has been added.

Claims 14, 17, 20, 23-25, and 30-38 are now pending and in condition for allowance.

## **II. Rejections under 35 U.S.C. §112**

### **A. Claims 14, 17, 20, and 24-25 satisfy the enablement requirement of 35 U.S.C. §112, first paragraph**

Claims 14, 17, 20, and 24-25 are rejected under 35 U.S.C. §112, first paragraph as not complying with the enablement requirement. Applicants have further clarified claim 14 by including the phrase “at least 95% identical to SEQ ID NO:1, wherein the nucleic acid encodes an alpha subunit of an SCN1A sodium channel.” In light of the current claims this rejection is moot.

### **B. Claims 14, 17, 20, and 24-25 satisfy the written description requirement of 35 U.S.C. §112, first paragraph**

Claims 14, 17, 20, and 24-25 have been rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirements. Applicants have further clarified claim 14 by including the phrase “at least 95% identical to SEQ ID NO:1, wherein the nucleic acid encodes an alpha subunit of an SCN1A sodium channel.” In light of the current claims this rejection is moot.

**C. Claim 25 satisfies the written description requirement of 35 U.S.C. §112, first paragraph**

Claim 25 is rejected under 35 U.S.C. §112 as lacking written description for mutations at nucleotides 828, 3978, and 5582. Applicants respectfully traverse.

The genesis of this rejection is merely one of "point of reference." From the Actions perspective, A565T and the respective mutations at nucleotide 3978 and 5582 are identified using the A of the initiator ATG codon as nucleotide 1. By this convention amino acid 188 would be encoded by a total number of 564 nucleotides ( $188 \times 3 = 564$ ). SEQ ID NO:1 includes an additional 265 nucleotides 5' of the initiator ATG, thus in relation to SEQ ID NO:1 mutation at A565T is located at nucleotide 828 ( $564 + 265 = 829$  total nucleotides minus one = **828**; since the second nucleotide of codon 188 is mutated: from gAt, encoding aspartic acid to gTt, encoding valine [the D188V mutation "*The A565T substitution correspond to a non-conservative amino acid change (D188V).*" Page 55, lines 14-15]) when using the numbering of SEQ ID NO:1. Typically nucleic acid sequences are presented as there cDNA sequence that includes 5' non-translated (5'UT) regions that can be represented as negative numbers relative to the initiator codon. However, sequence listing conventions do not allow such numbering leading to the discrepancy identified in the Action. One of skill in the art would readily recognize this discrepancy and identify the A565T mutation at nucleotide position 828 of SEQ ID NO:1. This should also be clear from the enclosed initial copy of the sequences filed with the application (Annex 1), which shows the 5'UT as lower case letters and the coding region as upper case. Further more "Seq Id No:1" (Annex 2), the first sequence described in Annex 1, highlights the initiator ATG and the GAT codon of the 188<sup>th</sup> amino acid. With respect to the nucleotide position 3978 mutation (amino acid position 1238) and the nucleotide position 5582 mutation (amino acid position 1773) the support is easily identified, since for example, it should be clear

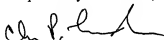
to the skilled artisan that the nucleotide sequences which are mutated: GCATTGAAGATATA OR ATCATATCCTTCCTG (Fig. 3 and page 52) are found between positions 3970-3984 (with "C" being at position 3978) and positions 5575-5589 (with "A" being at position 5582) of SEQ ID NO:1; respectively. Applicants respectfully request the withdrawal of the rejection.

### III. CONCLUSION

Applicants believe that the present document is a full and complete response to the Notice dated March 17, 2008. The present case is in condition for allowance, and such favorable action is respectfully requested.

The Examiner is encouraged to contact the undersigned Attorney at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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